

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: MENDEL-HARTVIG, Ib et al. Conf.:

Appl. No.: New Group:

Filed: May 4, 2001 Examiner:

For: ASSAY DEVICE WITH TIMER FUNCTION

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents  
Washington, DC 20231

May 4, 2001

Sir:

The following preliminary amendments and remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE CLAIMS:

Please amend the claims as follows:

5. (Amended) The device according to claim 1, characterized in that time indicator includes a hygroscopic substance.

6. (Amended) The device according to claim 1, characterized in that time indicator includes a filler substance.

7. (Amended) The device according to claim 1, characterized in that time indicator comprises a substance mixture attached to the wicking member or the inner side of the housing by tape.

8. (Amended) The device according to claim 1, characterized in that the time indicator comprises an indicator substance or substance combination applied to a support (14) which in turn is applied to the wicking member of inner side of the housing.

10. (Amended) A method of performing an assay for determining an analyte in a sample, characterized in that the method comprises the steps of:

- (i) providing an assay device as defined in claim 1, wherein the time indicator is placed in a selected position between the upstream end and the downstream end of the wicking member adapted to the assay to be performed,
- (ii) flowing sample and assay liquid(s) through the flow matrix of the device such that they reach the detection zone in a predetermined sequence, and
- (iii)** when the time indicator has changed colour indicating that a predetermined time has elapsed from the application of liquid to the liquid application zone, reading the result of the assay in the detection zone.

REMARKS

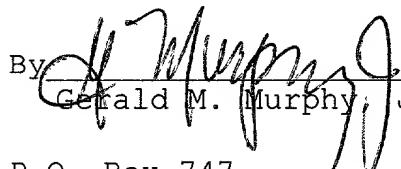
The amendment to the claims is merely to delete improper multiple dependencies and to place the application into better form for examination. Entry of the present amendment and favorable action on the above-identified application are earnestly solicited.

Attached hereto is a marked-up copy of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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GMM/cqc  
1614-0248P

Attachment: Version with Markings Showing Changes Made

(Rev. 01/22/01)

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

The claims have been amended as follows:

5. (Amended) The device according to [any one of claims 1 to 4]claim 1, characterized in that time indicator includes a hygroscopic substance.

6. (Amended) The device according to [any one of claims 1 to 5]claim 1, characterized in that time indicator includes a filler substance.

7. (Amended) The device according to [any one of claims 1 to 6]claim 1, characterized in that time indicator comprises a substance mixture attached to the wicking member or the inner side of the housing by tape.

8. (Amended) The device according to [any one of claims 1 to 6]claim 1, characterized in that the time indicator comprises an indicator substance or substance combination applied to a support (14) which in turn is applied to the wicking member of inner side of the housing.

10. (Amended) A method of performing an assay for determining an analyte in a sample, characterized in that the method comprises the steps of:

- (i) providing an assay device as defined in [any one of claims 1 to 7]claim 1, wherein the time indicator is placed in a selected position between the upstream end and the downstream end of the wicking member adapted to the assay to be performed,
- (ii) flowing sample and assay liquid(s) through the flow matrix of the device such that they reach the detection zone in a predetermined sequence, and
- (iii) when the time indicator has changed colour indicating that a predetermined time has elapsed from the application of liquid to the liquid application zone, reading the result of the assay in the detection zone.